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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/032,482	01/02/2002	Irun R. Cohen	COHEN=42A	5950

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EXAMINER	
AEDER, SEAN E	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 07/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/032,482	COHEN ET AL.	
	Examiner	Art Unit	
	Sean E. Aeder, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-12 and 17-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-12 and 17-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The request filed on 5/3/05 for a Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 10/032,482 is acceptable and a RCE has been established. Claims 8-12, and 17-28 are pending and are currently under prosecution. An action on the RCE follows.

Claims 8-12 have been amended.

Claims 1-7, 13-16 have been canceled.

Claims 18-28 have been added.

Claims 8-12 and 17-28 are under examination.

The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action.

The following Office Action contains NEW GROUNDS of rejections.

Claim Objections

Applicant, in addressing the objection to the claims for depending on non-elected inventions, states that claim 8 is a linking claim and all of the species are dependent and linked to this claim and the restriction should be a species election (see page 8 of response). In response to this argument, this is persuasive and the restriction between Groups XX-XXXVI is vacated and the examiner is not imposing a species election in

view that the claimed sequences of 7-30 amino acids in length are free of the art and as such the objection is withdrawn.

Claims 18, 23 are objected to because the claim should recite "mAb 240, mAb 246, and mAb 421" for consistency. Appropriate correction is required.

Rejections Withdrawn

The rejection of claims 8-11 and claims 12 and 17 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of arguments.

The rejection of claims 10-12 under 35 U.S.C. 112, first paragraph, is withdrawn in view of arguments.

The rejection of claims 8-10 and claim 12 under 35 U.S.C. 102(b) as being anticipated by Jannot et al (BBRC 230:242-246, 1/1997) is withdrawn in view of the amendments to the claims.

Response to Arguments

The rejection of claims 8-12, 17, and newly added claims 18-28 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained.

The response filed 5/3/05 has been carefully considered but is deemed not to be persuasive. The response states that applicants have amended the claims to recite the peptide is 7-30 amino acids in length and the specification teaches SEQ ID NO:9-14 and 18-23 which are within this range (see page 9 of response). In response to this argument, the claims still recite "contains" which is open language and the only peptides that contain the CDR sequences are in the context of peptides from mAb 240, mAb 246, and mAb 421. There is no disclosure of any CDR sequences that are not in this context as broadly encompassed in the claims. Thus, one of skill in the art would not understand that the applicant had possession of the claimed invention at the time the instant application was filed.

The rejection of claims 8-9, 17, and newly added claims 18-21, 27-28 under 35 U.S.C. 112, first paragraph, is maintained. The response filed 5/3/05 has been carefully considered but is deemed not to be persuasive. The response states that the specification defines "chemical derivative" and teaches such (see page 10 of response). In response to this argument, there is no evidence either in the specification or the prior art that derivatizing an amino acid in the CDR would or could elicit antibodies to p53.

This rejection is further applied to newly added claims 27 and 28 for the recitation of "chemical derivatives".

In addition, newly added claims 19 and 24 recite "based on" the CDR2 or CDR3 and this language broadly encompasses changing the CDR sequences (see 112 second rejection below) and there is no teaching in the specification that altering the CDR sequences would elicit antibodies to p53. As stated again, the art (Erez-Alon et al made of record) is clear that not all peptides from a CDR of an anti-p53 antibody can elicit anti-ids and in addition, as evidenced from the response filed 10/26/04 not all anti-p53 CDR peptides can elicit anti-id (see page 11 of response). Therefore, one skilled in the art would conclude that while not all CDRs can elicit antibodies, surely altering them would not elicit antibodies to p53. Thus, even the instant specification does not enable the breadth of the claims because it appears that not all CDRs from and anti-p53 antibody can elicit antibodies and altering such would not elicit antibodies.

Thus, the specification does not reasonably provide enablement for a peptide capable of eliciting antibodies to p53 wherein the peptide contains just any sequence of a CDR from just any anti-p53 antibody and salts and chemical derivatives thereof.

Therefore, in view of the lack of guidance in the specification and in view of the discussion above one of skill in the art would be required to perform undue experimentation in order to practice the claimed invention.

The following are NEW GROUNDS of rejections

Claims 19 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 19 and 24 are indefinite for reciting "based on the" CDR2 or CDR because it is not clear if the sequences recited are those claimed or are altered in some way such as alterations in the amino acid sequences. It is unclear what the peptides are "based on" means.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 8-9, 17, 20, 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zusman et al (The Cancer Journal 10:116-120, 1997) and further in view of Carson et al (US Patent 5,068,177, issued 11/91).

The claims recite a synthetic peptide capable of eliciting antibodies to p53 which peptide is 7-30 amino acids and contains a CDR sequence from an anti-p53 antibody and pharmaceutical compositions comprising such and the peptide obtained by a process (claim 28). The intended use for eliciting antibodies to p53 recited in the claims carries no patentable weight for this rejection.

Zusman et al teach tumor suppression effects with an anti-p53 IgG and "we suggest that the anti-p53 IgG serving as an anticancer vaccine stimulates the generation of anti-idiotypic antibodies in a way similar to that described in the literature" (see entire document, especially page 119 right column fourth paragraph). Zusman et al does not teach a synthetic peptide of the CDR from an anti-p53 mAb. These deficiencies are made up for in the teachings of Carson et al.

Carson et al teach synthetic peptides from CDRs of antibodies used to produce an anti-idiotypic response and pharmaceutical compositions comprising such (see entire document).

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to have produced a synthetic peptide from the CDR of a p53 mAb in view of Zusman et al and Carson et al. One of ordinary skill in the art would have been motivated to and had a reasonable expectation of success to have produced a synthetic peptide from the CDR of a p53 antibody because Zusman et al teach anti-p53 antibodies can produce anti-ids and Carson teaches synthetic peptides from the CDRs of antibodies that elicit anti-ids (see page 119), thus it would have been obvious to produce a synthetic peptide from the CDR.

Although the claims require a synthetic peptide and Carson teach synthetic methods this limitation is a product by process similar claim 28 and as such the method in which the peptides were produced is immaterial to their patentability. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product I in the product-by-process claim I is the same or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re* Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985). See also MPEP 2113. In addition, the claims are to products

and as such and as stated in the rejection since the peptide is from an anti-p53 Mab one would readily envisage a peptide from the CDR2 or 3 of the antibody of Zusman would produce anti-idiotypic antibodies because the antibody of Zusman produces such as speculated.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Claims 8-9, 17, 18, 19-21, 23-24, and 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zusman et al (The Cancer Journal 10:116-120, 1997) and further in view of Carson et al (US Patent 5,068,177, issued 11/91) and Jannot et al (BBRC 230:242-246, 1/1997).

The claims recite a synthetic peptide capable of eliciting antibodies to p53 which peptide is 7-30 amino acids and contains a CDR sequence from mAb 421 from CDr3 and pharmaceutical compositions comprising such and the peptide obtained by a process (claim 28). The intended use for eliciting antibodies to p53 recited in the claims carries no patentable weight for this rejection.

Zusman et al teach tumor suppression effects with an anti-p53 IgG and "we suggest that the anti-p53 IgG serving as an anticancer vaccine stimulates the generation of anti-idiotypic antibodies in a way similar to that described in the literature"

(see entire document, especially page 119 right column fourth paragraph). Zusman et al does not teach a synthetic peptide of the CDR from an anti-p53 mAb 421. These deficiencies are made up for in the teachings of Carson et al and Jannot et al.

Carson et al teach synthetic peptides from CDRs of antibodies used to produce an anti-idiotypic response and pharmaceutical compositions comprising such (see entire document).

Jannot et al teach the CDR2 and CDR3 amino acid sequences of an anti-p53 antibody 421 and they are within the range of 7-30 amino acids (see Figure 4).

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to have produced a synthetic peptide from the CDR of the mAb 421 antibody in view of Zusman et al, Carson et al, and Jannot et al.

One of ordinary skill in the art would have been motivated to and had a reasonable expectation of success to have produced a synthetic peptide from the CDR of the mAb 421 antibody in view of Zusman et al, Carson et al, and Jannot et al because Zusman et al teach anti-p53 antibodies can produce anti-ids and in view of Carson who teaches synthetic peptides from the CDRs of antibodies that elicit anti-ids, it would have been obvious to produce a synthetic peptide from the CDR. In addition, one of ordinary skill in the art would have been motivated to and had a reasonable

expectation of success to have produced the claimed peptides because Jannot et al teach the anti-p53 antibody mAb 421, which binds to p53, and it would have been obvious in view of Carson to synthesize the CDR2 or 3 region of the antibody of Jannot et al.

Although the claims require a synthetic peptide and Carson teach synthetic methods this limitation is a product by process similar claim 28 and as such the method in which the peptides were produced is immaterial to their patentability. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product I in the product-by-process claim I is the same or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re* Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985). See also MPEP 2113. In addition, the claims are to products and as such and as stated in the rejection since the peptide is from an anti-p53 Mab (which is the same Mab as applicant used) it would inherently produce anti-idiotypic antibodies.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Conclusion

No claim is allowed.

Summary

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Aeder, Ph.D. whose telephone number is 571-272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SEA

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